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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,297	12/23/2003	Jacobus M. Lemmens	SYN-0019A	7864

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MARK R. BUSCHER  
SYNTHON IP INC  
7130 HERITAGE VILLAGE PLAZA  
STE 202  
GAINESVILLE, VA 20155

EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/743,297

Applicant(s)

LEMMENS ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-4,9-17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-4,9-17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

1. This application is a divisional of SN 10/076,221. Claims 5-8, 18, 24 and 25 have been cancelled by preliminary amendment. Claims 1-4, 9-17, 19-23 are pending.
2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 9-17, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stemp et al. EP 190496 in view of Jacewicz GB 2297550 and Nishino et al. JP-200095780 (all cited on 1449).

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Stemp et al. disclosed process of making paroxetine and its salt employing the N-methyl starting material (p.32), through the N-phenylcarbamate (p.33) and forming the free base (p.51-52) then acid addition salt was prepared (p.51-52). The particular hydrolyzation step of phenylcarbamate to the paroxetine free base was described on pages 51-52.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

Stemp et al. disclosed all the elements of the claims **except** the reaction process employed single solvent system while the claims are drawn to co-solvent i.e. mixed solvent system. Jacewicz et al. '550 taught that using single or mixed solvent system in preparation of paroxetine salt is an optional choice for artisan in the field (see p.4-5). Nishino et al. taught that mix solvent with 5-16 times weight ratio (see translation p.3) is desirable in preparing high purity of the carbamoyl intermediates and the preferred alcohol is R3OH wherein R3 is lower alkyl, namely ethanol.

*Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)*

One skilled in the art is in possession of all the conventional teaching of the field. The above references placed the desirable choices of solvents and mixing in the use in the possession of artisan. One would be suggested of using the ethanol containing mixed solvent as the claims with variation of ratio **because** of the desirability taught by Nishino in resulting purer intermediates. In absence of unexpected results, the picking and choosing of a mixed solvent among the conventionally known useful solvents (see Jacewicz examples using ethanol, isopropanol and toluene) and instead of a single solvent system is prima facie obvious in view of the large number of operable solvents conventionally known for such preparation found in

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Jacewicz (whole article) or Nishino (whole article), with motivation of choosing mixture which was suggested to aid in high purity of the intermediate material.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stemp et al. EP 190496 in view of Jacewicz GB 2297550 and Nishino et al. JP-200095780 further in view of Benneker et al. US 5,874,447.

The same rationale for finding claims 1-3, 11-17, 19-22 prima facie obvious over Stemp et al. EP 190496 in view of Jacewicz GB 2297550 and Nishino et al. JP-200095780 as delineated supra is also applicable here and incorporated by reference. The instant claim 23 of preparation for an alternative salt is also an art recognized variation in paroxetine salt preparation conventionally taught by Benneker '447 see whole article, especially, columns 3-6.

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4 and 10 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3 and 5 of prior U.S. Patent No. 6,686,473. This is a double patenting rejection.

5. Claims 1-3, 9, 11-17, 19-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-20 of U.S. Patent No. 6,686,473. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are more limited in the cosolvent having a broadened scope of the aliphatic alcohol, while the copending claims have the more limited aliphatic alcohol with a broadened cosolvent. Since mixed solvent is a well recognized variation of the instant art (see

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Stemp, Jacewicz and Nishino *supra*), the mix and match of the scope of how to mix variations of solvent is *prima facie* obvious.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

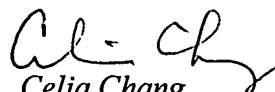
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message *supra*.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

OACS/Chang  
Mar. 6, 2006

  
Celia Chang  
Primary Examiner  
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